Appl. No. : 10/758,495
Filed : January 15, 2004

REMARKS

Prior to entry of the foregoing amendments, Claims 55-80 stand pending in the present application. Applicants have amended independent Claims 55 and 68. Thus, currently, Claims 55-80 stand pending and are believed to be allowable.

RESPONSE TO CLAIM REJECTIONS

The Examiner rejected Claims 57 and 60 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The Examiner also rejected Claims 68, 70-73 and 78 under 35 U.S.C. §102(e) as being anticipated by Lebel. Next, the Examiner rejected Claims 55, 56, 58, 59, 61-66, 69, 71, 74-78 under 35 U.S.C. §103(a) as being unpatentable over Silver 6442413 in view of Lebel. Finally, the Examiner rejected Claims 67, 79, and 80 under 35 U.S.C. §103(a) as being unpatentable over Silver 6442413 in view of Lebel and further in view of Kaylor. Applicants respectfully disagree with the propriety of the Examiner's various rejections.

Rejection under 35 U.S.C. § 112, ¶ 1

The Examiner stated that Claims 57 and 60 lacks a written description in that the specification does not discuss the streamlined sensor on a catheter or opening through a side wall of a support. The Examiner stated that these claims constitute new matter. Applicants respectfully traverse this rejection.

As stated by the Federal Circuit, "[t]he written description requirement does not require the applicant 'to describe exactly the subject matter claimed, [instead] the description must clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed.' Thus, § 112 ¶ 1 ensures that, as of the filing date, the inventor conveyed with reasonable clarity to those of skill in the art that he was in possession of the subject matter of the claims." *Union Oil Co. of California v. Atlantic Richfield Co.*, 208 F.3d 989, 54 USPQ2d 1227 (Fed. Cir. 2000) (internal citations omitted). "In order to satisfy the written description requirement, the disclosure as originally filed need not provide in haec verba support for the claimed subject matter at issue." *Lampi Corp. v. American Power Products, Inc.*, 228 F.3d 1365, 56 USPQ2d 1445 (Fed Cir. 2000) (internal citations omitted) For example, "[d]rawings constitute an adequate description if they describe what is claimed and convey to those of skill in the

art that the patentee actually invented what is claimed." *Cooper Cameron Corp. v. Kvaemer Oilfield Products, Inc.*, 291 F.3d 1317, 62 USPQ2d 1846 (Fed. Cir. 2002) (internal citations omitted).

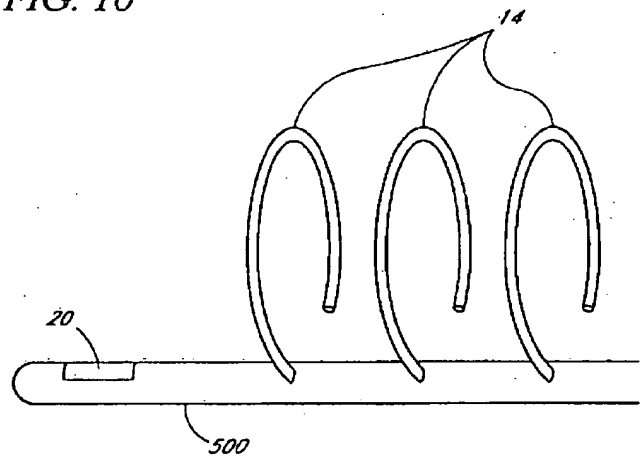
Here, the specification contains a more than sufficient description of a streamlined sensor on a catheter. The specification teaches in paragraph [0056] that "the support structure can either be a catheter or a stent." In addition, the specification contains numerous passages describing a streamlined sensor on a support structure. For example, the specification states at paragraph [0042] that: "One feature of the device is that the sensor surface is placed at the apex of the luminal surface of a streamlined housing." Paragraph [0045] of the specification states that "[a] sensor housing is carried by the support structure, the housing having a streamlined exterior configuration to minimize blood flow turbulence." Paragraph [0167] states that: "The sensor housing should be given a streamlined shape, with gradually sloped transitions at both its proximal and distal ends, in order to minimize flow disturbances. The housing should be as wide or wider at its base than at its apex." The specification states in paragraph [0180] that "the sensor should be designed with a streamlined profile at both its proximal and distal ends, to minimize regions of hemostasis." The specification goes on to state in paragraph [0210] that "[t]he proximal tip of the sensor is preferably in a streamlined configuration, such as a parabola or a cone, to minimize the risk of thrombus formation." Thus, the specification describes a streamlined sensor in conjunction with a catheter.

The specification also includes teaching of an opening through a side wall of a support. For example, Figure 16 shows a catheter with "sensing surface 20 oriented toward the vessel lumen." (*See* Paragraph [0220].) Implicitly, in order for the sensor 20 to be mounted on the catheter, flush with the catheter as shown in Figure 16, any sensor housing having non-zero thickness would be positioned within an opening on the side wall of the catheter.

The specification describes Figure 16 in paragraph [0220]: "As shown in Figure 16, the anchoring platform 14 is connected to a catheter 500, which contains multiple sensors 20, such as optode sensors, for monitoring pH, pO_2, and pCO_2, near its distal end. As in other embodiments, the anchors are made of a self-expanding material such

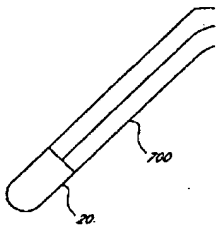
as nitinol. As previously described, these anchors help to position the sensor near the wall, with the sensing surface 20 oriented toward the vessel lumen."

FIG. 16



Another example of a catheter as a support structure is shown in Figure 18, and described in paragraph **[0243]**: "In an alternative embodiment, as shown in Figure 18, the nitric oxide or nitrite or nitrate sensor 20 may be incorporated ***into*** the distal end of a catheter-like tube 700". Thus, the specification implies the sensor housing must lie within an opening in the catheter support structure because of the incorporation of the sensor ***into*** the end of the catheter. The relevant portion of Figure 18 is shown below.

FIG. 18



The sensor 20 mounted on a catheter as described in both Figures 16 and 18 are wider at its base (which is a chord of a circle) than its apex (which is a single point at the top of the arc designated by that chord).

In addition, the specification elsewhere describes positioning the sensor through the sidewall of the support. For example, the specification teaches in paragraph [0111] that "the sensor 20 may be positioned in an aperture which is cut in the sidewall of the stent 14." Similarly, the specification states in paragraph [0112] that "the stent struts or other elements which make up the sidewall 18 may be removed or modified at the portion of the sidewall corresponding to the sensor 20 such that the sensor 20 may be mounted within the resulting opening in the sidewall." Later in that same paragraph, the specification states that, "...any reduction in radial support which may result from reasonably dimensioned apertures or other modifications to the sidewall to attach sensor 20 will not adversely affect the role of the stent as a sensor support structure in the context of the present invention."

The specification goes on in paragraph [0117] to teach that "in an embodiment in which the sensor 20 is positioned on the luminal side of the tubular side wall 18, or within or through an opening in the tubular sidewall 18, the sensor surface may be positioned directly on a radially inwardly-most extending portion of the sensor 20 as is discussed elsewhere herein." As an example, Figure 5B shows a sensor positioned through the sidewall of a support.

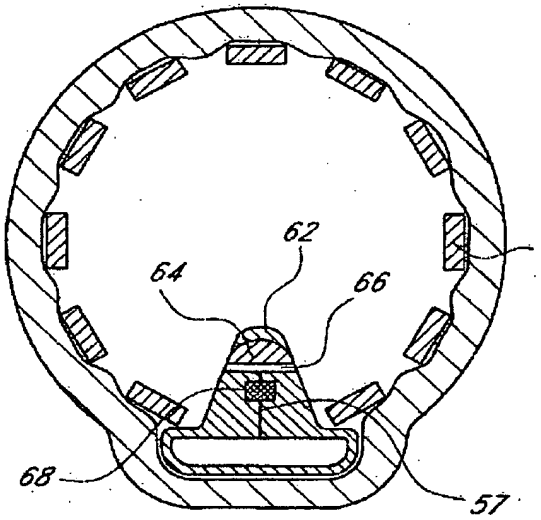


FIG. 5B

Thus, because the specification describes the claimed inventions of Claims 57 and 60 in sufficient detail that one skilled in the art could reasonably conclude that the inventor had possession of the claimed subject matter at the time the application was filed, the written description requirement is met. M.P.E.P. § 2163. Accordingly, Applicants respectfully request that the Examiner withdraw this rejection.

Rejection under 35 U.S.C. §102(e)

The Examiner rejected Claims 68, 70-73 and 78 under 35 U.S.C. §102(e) as being anticipated by Lebel. Applicants respectfully traverse this rejection.

The Examiner stated that "oxygen is a metabolite of NO." Though Applicants disagree with the Examiner's characterization, Applicants have amended Claim 68 to recite "a metabolic product of" NO, instead of a NO "metabolite" to further differentiate the claim from the alleged teachings of Lebel. Lebel does not teach or suggest sensing nitrites or nitrates or any other metabolic product of NO. Accordingly, Applicants respectfully request that the Examiner withdraw the rejection and pass these claims to allowance.

Rejection under 35 U.S.C. §103

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The Examiner rejected Claims 55, 56, 59, 61-66, 69, 71, 74-78 under 35 U.S.C. §103(a) as being unpatentable over Silver 6442413 in view of Lebel. Applicants do not agree with the propriety of the Examiner's rejections. Applicants have amended Claims 55 and 68 to further differentiate the claims from the cited art. Claims 55 and 68 now recite, among other things, that the "sensing surface includes a layer that minimizes the formation of thrombus." The cited art does not disclose or suggest all the features of Claim 55 and 68. Accordingly, Claim 55 and 68 are believed to be allowable. Claims 56 – 67, which depend from Claim 55, and Claims 69 – 80, which depend from Claim 68, are believed to be allowable for the same reasons articulated above with respect to Claims 55 and 68, and because of the additional features recited therein. Accordingly, Applicants respectfully request that the Examiner withdraw the rejections and pass claims 55-80 to allowance.

CONCLUSION

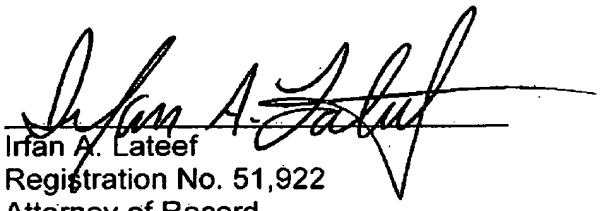
If the Examiner finds any remaining impediment to the prompt allowance of these claims that could be clarified with a telephone conference, the Examiner is respectfully requested to initiate the same with the undersigned.

Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

KNOBBE, MARTENS, OLSON & BEAR, LLP

Dated: September 11, 2006

By: 

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